

Appl. No. 10/781,062
Amendment dated June 9, 2006
Reply to Office Action of March 9, 2006

Remarks

Claims 1, 8-10, 13, 14, and 17-22 are all the claims pending in the above-identified application prior to entry of this Amendment. Claims 1, 9, 10, 13, 17 and 21 have been amended. Accordingly, after entry of this Amendment, Claims 1, 8-10, 13, 14, and 17-22 are pending in this case. The changes to the claims do not constitute the addition of new matter and full support for the changes may be found in the specification and claims as originally filed. In this Amendment, Claims 9, 10 and 13 have been amended to delete subject matter directed to the non-elected invention, and Claims 17 and 21 are amended to correct typographical errors.

Restriction Requirement

Restriction of the claims was required. The claims were separated in the following groups:

- Group I: Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0) where Y represents C and both B1 and B2 represent saturated or unsaturated carbocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 290.
- Group II: Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0) where Y represents N and both B1 and B2 represent saturated or unsaturated carbocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 544, subclass 333.
- Group III: Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0) where Y represents C and both B1 and B2 represent saturated or unsaturated heterocyclic ring, pharmaceutical compositions

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containing these compounds and a method of using these compounds, classified in class 540, subclass 450.

Group IV: Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0) where Y represents N and both B1 and 82 represent saturated or unsaturated heterocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 540, subclass 470.

Group V: Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0) where Y represents C, B1 represents saturated or unsaturated carbocyclic ring and B2 represents a saturated or unsaturated heterocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 255.

Group VI: Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0) where Y represents N, B1 represents saturated or unsaturated carbocyclic ring and 82 represents a saturated or unsaturated heterocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 544, subclass 242.

Group VII: Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0) where Y represents C, B1 represents a saturated or unsaturated heterocyclic ring and B2 represent saturated or unsaturated carbocyclic ring, pharmaceutical compositions containing these compounds and a

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method of using these compounds, classified in class 546, subclass 268.1.

Group VIII: Claims 1, 8-10, 13, 14 and 17-22, drawn to compounds of formula (1.0.0) where Y represents N, B1 represents a saturated or unsaturated heterocyclic ring and B2 represents a saturated or unsaturated carbocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 544, subclass 298.

In a telephone conversation on March 3, 2006, the Applicants' representative, Mr. Phillip Polster, made a provisional election, with traverse, of Group I, claims 1, 8-10, 13, 14, and 17-22, drawn to compounds of formula (1.0.0) where Y represents C and both B1 and B2 represent saturated or unsaturated carbocyclic rings, pharmaceutical compositions containing these compounds and a method of using these compounds. The Applicants affirm this election of Group I. According to the Office Action, Claim 8 has been withdrawn by the Examiner as being drawn to a non-elected invention. Applicants traverse the designation of claim 8 as drawn to a non-elected invention and respectfully request that the Examiner reconsider. For this reason, Applicants have not designated claim 8 as withdrawn. Applicants have amended Claims 1, 9, 10 and 13 to delete the non-elected subject matter. The Applicants reserve the right to pursue the remaining claims and subject matter in divisional or continuation applications.

Amendment of the Specification

The Abstract has been amended as requested by the Examiner to shorten it.

Rejection Under 35 U.S.C. §102(b)

The Examiner has rejected claims 1, 9, 10, 13 and 17-22 under 35 U.S.C. §102(b) as allegedly anticipated by Marfat (WO 98/45268). The Examiner alleges that

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Marfat compounds in examples 229 and 285 anticipate the instant claims when j is 1, R³ is H, n is 1, w is O, B¹ is phenyl and B² represents either a phenyl group or a cyclohexyl group in the compounds of formula (1.0.0).

Claim 1 has been amended to specify that when M is O, R⁷ cannot be C₁alkyl group (methyl) when R⁹ is hydrogen and R⁹ cannot be C₁alkyl group (methyl) when R⁷ is hydrogen.

In view of these amendments, reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b) is respectfully requested.

Rejection Under 35 U.S.C. §112, First Paragraph

The examiner has rejected claims 18-22 as allegedly failing to comply with the enablement requirement of 35 U.S.C. §112, first paragraph. This rejection is respectfully traversed.

The Examiner acknowledges that the instant compounds are inhibitors of the PDE4 isozyme. The Examiner's rejection is based on the statement that "the instant compounds will have utility in treating only those disease conditions where structurally closely related PDE 4 inhibitors are well known in the prior art to have therapeutic utility."

The Examiner states that "(t)here is no teaching either in the specification or prior art that PDE4 isozyme mediates all the disease conditions listed in instant claims 20 and 21. . . ." Applicants traverse this statement. In fact the specification itself teaches that the claimed compounds are useful for the treatment of the listed diseases. The Examiner has provided no evidence to contradict the assertion in the specification that the claimed compounds would be useful for treating the diseases listed in claims 20 and 21.

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The law on enablement, as clearly set forth by the Federal Circuit's predecessor court in In re Marzocchi, requires the Patent Office to provide specific reasons for a §112 rejection:

As a matter of patent office practice...a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of §112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

In re Marzocchi, 439 F.2d 220, 223-224 (C.C.P.A. 1971) (emphasis in the original).
Furthermore, the evidence or reasoning supplied by the Examiner must be particularized and definite, not broad and general:

[W]e do not consider that a broad allegation that the application disclosure is speculative, coupled with a recitation of various difficulties which might be encountered in attempting to put it into practice, and a further assertion that there might still be other difficulties which would not be foreseen, constitutes a sufficiently definite statement of a basis for rejection.

In re Chilowsky, 229 F.2d 457, 462 (C.C.P.A. 1956).

Applicants submit that no undue experimentation is required to practice the invention as claimed in claims 20 and 21. Claim 20 and 21 relate to a method for treating a subject suffering from a disease, disorder or condition mediated by PDE4 isozyme. Throughout the specification the discussion of the effects of PDE4 isozyme on many other systems are discussed and the relationship of this isozyme to the multitude of disease states and conditions is discussed. The application on pages 100 through 135 describes the therapeutic applications to which the claimed compounds

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may be put. In vitro assays and animal model experiments are also clearly described to provide data sufficient to demonstrate the therapeutic utility or to test the compounds of formula (1.0.0). Treatment of the listed conditions is well within the skill of the person of ordinary skill in the art. A person of ordinary skill in the art would know or could readily determine the quantity of, for instance, a compound of formula (1.0.0) required to treat a listed condition. Accordingly, no undue experimentation would be required to practice the invention claimed in claims 20 and 21.

In view of these amendments and remarks, withdrawal of the rejections under 35 U.S.C. §112, first paragraph, is respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 1, 17-19 and 22 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

Claim 1

The Examiner has correctly noted that in claim 1, page 4, the term "*" is indefinite in that it is defined to indicate the point of attachment of each partial Formula (1.1.1) through (1.1.5), where formulae (1.1.1), (1.1.2), (1.1.4) and (1.1.5) have been previously deleted. Applicants thank the Examiner for his observation and have amended the definition of "*" in claim 1 to remove the superfluous language. Applicants respectfully request that the examiner reconsider his rejection in light of this amendment and withdraw this rejection.

Claim 17

Similarly, Applicants have amended claim 17 to delete the superfluous words "of formula" from line 4.

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Claims 18 and 19

The Examiner alleges that the term "mediated by the PDE4 isozyme" in claims 18 and 19 is indefinite in the absence of specific disease conditions. Applicants respectfully traverse this rejection and request reconsideration. The term "disease, disorder or condition mediated by the PDE4 isozyme" is not indefinite. The claims are to be read in light of the specification. As noted above, the specification sets forth over 35 pages of conditions that are mediated by PDE4 isozyme. All conditions do not have to be set forth in the claims as long as they are adequately described in the specification.

Applicants respectfully request that the Examiner reconsider his rejection of claims 18 and 19 in light of these remarks and withdraw this rejection.

In view of these amendments and remarks, withdrawal of the rejections under 35 U.S.C. §112, second paragraph, is respectfully requested.

Rejection Under 35 U.S.C. §101,

Claim 19 is rejected under 35 U.S.C. §101 for reciting a process without setting forth any steps involved in the process. Applicants respectfully traverse this rejection and request reconsideration. Claim 19 is directed to a pharmaceutical composition for use in treating a subject suffering from disease, disorder or condition mediated by the PDE4 isozyme. Claim 19 itself is not a process claim, but claims a composition. Applicants respectfully request that the Examiner reconsider his rejection of claim 19 under 35 U.S.C. §101 in light of these remarks and withdraw this rejection.

The above discussion and corresponding amendments are based on section 101 and 112 issues and are not made to overcome art-based rejections. Accordingly, such discussion and corresponding amendments should not be construed in a limiting manner.

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It is respectfully submitted that the claims have been put in condition for allowance. Notification to this affect is earnestly solicited. The Examiner is encouraged to contact the Applicants' undersigned attorney to discuss this matter if any questions should arise upon further examination of the pending claims.

Respectfully submitted,

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